IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	**:**	
v.	**:**	**CRIMINAL NO.**
NOVARTIS PHARMACEUTICALS CORPORATION	**:**	

GOVERNMENT'S MEMORANDUM FOR ENTRY OF PLEA AND SENTENCING

I. INTRODUCTION

The United States hereby submits its Memorandum for Entry of Plea and Sentencing. For the reasons outlined below, the government respectfully submits that the Court should accept the guilty plea of Novartis Pharmaceuticals Corporation ("NPC"), and sentence NPC in accordance with the parties' agreement.

The government has filed an information charging NPC with one count of misbranding under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"). The government and NPC have executed a guilty plea agreement pursuant to Fed.R.Crim.P. 11(c)(1)(C), under which, with the Court's approval, it will plead guilty to the information, and pay a stipulated penalty of $185,000,000 (including a criminal fine of $170,000,000 and $15,000,000 in criminal forfeiture). The plea agreement also proposes that the Court proceed to impose sentence immediately, without conducting a presentence investigation.

The plea agreement resolves a significant criminal investigation into the promotional practices in the United States of NPC for its anti-epileptic drug Trileptal. The essence of the

charge is that NPC marketed Trileptal for uses that had not been approved by the Food and Drug Administration ("FDA"), which resulted in the drug being misbranded. This guilty plea is part of a global resolution that will include a civil settlement agreement with the United States and many states, a Corporate Integrity Agreement with the Department of Health and Human Services, Office of the Inspector General, and resolution of several civil actions brought under the qui tam provisions of the False Claims Act.

II. THE CRIMINAL CHARGE

The information filed in this case charges NPC with one count of misbranding its prescription drug Trileptal under the FDCA, 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1). A copy of this information is attached as Exhibit A.

As the information explains, the FDCA governs the interstate distribution of drugs for human use. The FDCA, and its implementing regulations, prohibit the sponsor of a new drug from distributing that drug in interstate commerce until the sponsor has obtained approval from the FDA, after an intensive application and review process. (Information, par. 3). To obtain that approval, the sponsor must file a New Drug Application ("the application") with the FDA, which identifies all of the uses of the drug intended by the sponsor, and includes proposed labeling for those uses. The sponsor must also provide data based on proper clinical trials that demonstrates to the FDA's satisfaction that the drug would be safe and effective for those intended uses. 21 U.S.C. §§ 331(d) and 355(b). (Information, par. 4).

The sponsor can only distribute the drug once the FDA approves the application and the labeling for the drug. The approved labeling includes those uses of the drug, proposed by the sponsor, which the FDA has approved. Uses not approved by the FDA, and thus not included in

the labeling for the drug, are unapproved or "off-label" uses. Once the FDA approves the drug, the sponsor can promote the drug, but only for those uses which the FDA approved. If the sponsor wants to promote the drug for a new use, the sponsor must apply to the FDA, support the new use with the proper data from studies, propose appropriate labeling, and obtain FDA approval. (Information, pars. 5-6).

Under the FDCA, a drug is misbranded if the labeling does not bear adequate directions for use. Adequate directions for use can only be written for uses for which the drug has been found by the FDA to be safe and effective. Drugs promoted for uses that have not been approved by FDA are misbranded under Section 352(f)(1), and thus can not be distributed in interstate commerce. (Information, pars. 7-8).

The information alleges that NPC misbranded Trileptal by marketing it for off-label uses from July 2000 through at least June 2004. (Information, par. 17). In January 2000, the FDA had approved Trileptal for the treatment of partial seizures in persons with epilepsy. (Information, par. 9). When sales of Trileptal did not meet expectations, NPC re-launched the drug to market Trileptal for the unapproved uses of neuropathic pain and bipolar disease, and profited from this off-label campaign by hundreds of millions of dollars. (Information, pars. 13, 16, and 24).

The information specifically charges that NPC introduced and caused the introduction into interstate commerce of Trileptal, a drug which was misbranded because it lacked adequate directions for its use, in that NPC promoted it off-label, from July 2000 through December 2001. (Information, par. 25). This is the charge to which NPC is pleading guilty.

III. THE GUILTY PLEA AGREEMENT

The essential terms of the plea agreement are set forth here. (A complete copy is attached for the Court's reference as Exhibit B.) In particular:

- NPC agrees to plead guilty to a one-count information charging misdemeanor misbranding of its drug Trileptal through its illegal promotion between July 2000 and December 2001, in violation of the FDCA, 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1). NPC also agrees not to contest forfeiture as set forth in the agreement. (Plea Agreement, par. 1).

- The parties entered into this plea agreement under Fed.R.Crim.P. 11(c)(1)(C), with a stipulated sentence. (Plea Agreement, par. 2).

- The agreed-upon sentence is: payment of $185,000,000 ($170,000,000 as the criminal fine, plus $15,000,000 as the criminal forfeiture), all payable within 10 business days of sentencing; plus the special assessment of $125. In light of the anticipated Corporate Integrity Agreement, the parties agree that NPC will not be placed on probation. (Plea Agreement, par. 2).

- The parties stipulate to the following facts and basis for the plea, criminal fine and forfeiture (Plea Agreement, par. 6(A)):

  (1) NPC marketed Trileptal, which was a drug within the meaning of 21 U.S.C. § 321(g)(1).

  (2) Shipments of a drug in interstate commerce must be accompanied by labeling bearing adequate directions for use for each of the drug's intended uses.

  (3) In January 2000, the FDA approved Trileptal as adjunctive or monotherapy for the treatment of partial seizures in adults with epilepsy, and as adjunctive therapy for the treatment of partial seizures in children ages 4-16 with epilepsy. Later in January 2000, the FDA approved an expansion of Trileptal's label to include its use in children over 2 years old. On August 7, 2003, the FDA approved an expansion of Trileptal's label to include its use as monotherapy in the treatment of partial seizures in children ages 4-16 with epilepsy.

  (4) Between July 2000 and December 2001, NPC promoted Trileptal as treatment for bipolar disorder and neuropathic pain. Trileptal is not approved by the FDA for treatment of bipolar disorder and neuropathic pain. NPC's promotion of Trileptal for these additional intended uses violated 21 U.S.C. § 352(f)(1), because Trileptal's labeling did not bear adequate directions for each of the drug's intended uses.

- The United States contends that, as a matter of relevant conduct, the conduct at issue continued past December 2001. NPC does not admit that this conduct extended past December 2001. (Plea Agreement, par. 6(B)).

- The Plea Agreement contains a non-prosecution clause for conduct which (A) falls within the scope of the criminal investigation in the Eastern District of Pennsylvania relating to NPC's drug Trileptal; or (B) was known to the United States Attorney's Office for the Eastern District of Pennsylvania or the Office of Consumer Litigation of the Department of Justice as of the date of the execution of this plea agreement, and which concerned the sale, promotion, or marketing of Trileptal in the United States. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the Eastern District of Pennsylvania, the Office of Consumer Litigation of the Department of Justice, the United States Attorney's Offices for each of the other 93 judicial districts of the United States, and the Criminal Division of the United States Department of Justice. (Plea Agreement, pars. 8-9).

- The Plea Agreement contains an appellate waiver. There can be no appeal if the Court enters the plea under Rule 11(c)(1)(C). (Plea Agreement, par. 11).

- If acceptable to the Court, the parties agree to waive the presentence investigation and report pursuant to Fed.R.Crim.P. 32(c)(1), and ask that NPC be sentenced at the time the guilty plea is entered. (Plea Agreement, par. 15).

IV. THE OTHER COMPONENTS OF THE GLOBAL RESOLUTION

The plea agreement is part of a global resolution reached between the United States and NPC concerning Trileptal and other NPC drugs. In a separate civil settlement among the United States, Medicaid-participating states, and NPC, NPC will pay $237,500,000, to resolve claims by the United States Medicaid and Medicare Trust Funds, and other federal agencies. This settlement also resolves four pending qui tam actions. Along with the civil settlement, NPC is executing a five-year Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services, Office of the Inspector General. This agreement will impose a strict compliance program to ensure that the conduct does not recur, and penalties for any non-compliance by NPC.

V. THE ESSENTIAL ELEMENTS OF THE OFFENSE

A. Misbranding

The information charges one count of misbranding under the FDCA, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1). Section 331 lists prohibited acts, including:

> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

Section 352 of the FDCA defines a drug as "misbranded" under several circumstances, including (as relevant here):

> A drug or device shall be deemed to be misbranded –
>
> (f) Directions for use and warnings on label
> Unless its labeling bears (1) adequate directions for use . . . .

Section 333 sets forth misdemeanor and felony penalties for violations of Section 331:

> (a) Violation of section 331 of this title; second violation; intent to defraud or mislead
>
> > (1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
> >
> > (2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

The information in this case charges a misdemeanor under 21 U.S.C. § 333(a)(1). In order to prove this crime, the government must establish the following elements beyond a reasonable doubt:

- that Trileptal is a drug
- that Trileptal was misbranded in that it lacked adequate directions for the uses intended by NPC, and

- that Trileptal was introduced into interstate commerce.

It is not illegal for a doctor, using good medical judgment, to prescribe a drug for an off-label use. However, it constitutes criminal misbranding for a drug manufacturer to promote its drug for such off-label use to that doctor.

B. Forfeiture

The forfeiture component of the information and plea agreement arises from the FDCA's provision for seizing misbranded drugs. 21 U.S.C. § 334 (allowing proceedings on libel of information, for condemnation, against drugs that are misbranded or adulterated so that the government can seize, destroy or sell them). These proceedings are by their nature classic civil forfeiture proceedings. Under federal forfeiture law, the government can pursue criminal forfeiture in any case where the defendant is charged with a violation of an Act of Congress which contains a civil forfeiture remedy. See 28 U.S.C. § 2461(c) (allowing criminal forfeiture where the defendant is charged "in a criminal case with a violation of an Act of Congress for which the civil or criminal forfeiture of property is authorized . . . ."). Thus, if civil forfeiture is authorized in a statute such as the FDCA, then criminal forfeiture is as well.

As the misbranded drugs are no longer available for seizure or destruction, the government can seek substitute assets. See 18 U.S.C. § 2461(c) (the procedures set forth in 21 U.S.C. § 853 apply to this criminal forfeiture); 21 U.S.C. § 853(p) (allowing the forfeiture of substitute assets if the items subject to forfeiture are no longer available).

VI. THE MAXIMUM PENALTIES

The maximum penalty for this offense is a fine of $200,000 (under 18 U.S.C.

§ 3571(c)(5)), or twice the gross gain or gross loss, whichever is greater (18 U.S.C. § 3571(d)); a special assessment of $125 (18 U.S.C. § 3013(a)(1)(B)(iii)); and a five-year term of Court supervision (18 U.S.C. § 3561(c)(2)); in addition, forfeiture may be ordered.

VII. THE FACTS AT TRIAL

In the plea agreement, the parties have stipulated to a factual basis sufficient to support the entry of this plea. (Plea Agreement, par. 6(A)). If the case were to proceed to trial, the government would prove these facts beyond a reasonable doubt, as well as each of the other allegations set forth in the information.

At trial, the United States would show that NPC developed a concerted plan to maximize revenue by the off-label marketing of Trileptal from July 2000 through June 2004. The FDA approved Trileptal in January 2000 for the treatment of partial seizures in persons suffering from epilepsy. Epilepsy is a brain disorder where the brain function is disturbed by spontaneous seizures caused by abnormally excited electrical signals. The disease is normally treated by neurologists and specialists called epileptologists. NPC's initial launch of the drug was on-label, with its marketing plan targeting neurologists primarily.

Within months of the launch, the sales of Trileptal were not reaching the levels that NPC projected and wanted. NPC knew that doctors were prescribing other anti-epileptic drugs for bipolar disease and neuropathic pain. Doctors, of course, can prescribe medications off-label if that is their best medical judgment, and the use of anti-epileptic drugs was increasing in the treatment of those diseases. NPC also knew that the populations suffering from these disorders greatly outnumbered the population of epileptics in the United States. NPC thus decided to compete for the off-label markets of bipolar disease and neuropathic pain.

By June 2000, with the approval of its top management, NPC had reformulated its promotion strategy, and re-launched Trileptal to capture the market opportunities in bipolar disease and neuropathic pain. NPC directed its sales staff to call on doctors who treated bipolar disease and neuropathic pain, in particular psychiatrists, neurologists and pain doctors. NPC trained its sales staff in these off-label diseases, and provided them with studies and materials to distribute to doctors about those off-label uses. In effect, sales representatives could only meet their company sales goals by promoting Trileptal off-label. NPC also used Continuing Medical Education programs and Advisory Boards to advance off-label sales.

This re-launch was successful, and sales increased significantly in the psychiatric and pain markets. At the same time, NPC knew that clinical studies in the 1990s had failed to show that Trileptal was effective for bipolar disease, and NPC lacked data to show that the drug was effective in neuropathic pain. When NPC undertook clinical studies to test the efficacy of Trileptal for neuropathic pain, those tests also failed to show positive results.

The government would also prove that NPC effectively ended its off-label promotion as of June 2004.

VIII. THE SENTENCING CONSIDERATIONS

The agreed-upon sentence takes into account NPC's conduct under 18 U.S.C. §§ 3553 and 3572, and the United States Sentencing Guidelines. The proposed sentence reflects the breadth and length of the company's illegal conduct, including relevant conduct relating to the off-label promotion of Trileptal.

The criminal fine is based on the procedure set forth in the Sentencing Guidelines (§ 8C2). The agreed-upon fine represents the government's best estimate of how much Trileptal

NPC sold unlawfully from July 2000 through June 2004, and how much profit NPC derived from those sales, with an appropriate multiplier based on the government's assessment of NPC's culpability score. The resulting penalty totals $185,000,000, of which $15,000,000 is allocated to asset forfeiture. This agreed-upon sentence falls within the statutory maximum set forth in 18 U.S.C. § 3571(d) (twice the gross gain or loss).

The proposed criminal resolution accomplishes the goals of sentencing under 18 U.S.C. § 3553(a). It is the product of extensive negotiations between the parties, addressing the seriousness, nature and circumstances of the offense, and the history and characteristics of the defendant. It also reflects the harm caused by the off-label marketing, which undermined the drug approval process mandated by statute, interfered with the doctor-patient relationship, was misleading to doctors, and posed risk to patients. This fine promotes respect for the law, and will deter NPC and other companies in the industry from further unlawful promotion of its drugs. A criminal fine of this magnitude, coupled with all of the other aspects of the resolution of this matter, will also serve as general deterrence to others who might be tempted to engage in unlawful off-label marketing.

All of the factors discussed in this section are difficult to quantify, but the United States believes the proposed criminal penalty is a just resolution of this matter, particularly when coupled with the significant civil settlement and the obligations imposed by the Corporate Integrity Agreement.

IX. CONCLUSION

For these reasons, the United States respectfully recommends that the Court sentence NPC to a criminal fine in the amount of $170,000,000, impose asset forfeiture in the amount of

$15,000,000, and require a special assessment of $125. The United States also asks that the Court impose this sentence at the entry of plea hearing.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Memorandum was served upon defense counsel by hand-delivery and email, on this 30th day of September, 2010, as follows:

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